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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/688,925 | 10/21/2003 | Geertruida M. Veldman | 08702.0020-00000 | 2555 |

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| EXAMINER | |
|---|---|
| KEMMERER, ELIZABETH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/688,925 | VELDMAN ET AL. | |
| | Examiner | Art Unit | |
| | Elizabeth C. Kemmerer, Ph.D. | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 30, 3-35, 37, 41, and 42, drawn to an antibody, classified in class 530, subclass 387.1.

II. Claims 12-23, 32, and 36, drawn to methods of treatment comprising administering the antibody, classified in class 424, subclass 130.1.

III. Claims 24-29 and 38-40, drawn to nucleic acids encoding an antibody, vectors and host cells comprising the nucleic acid, and methods of recombinantly expressing the antibody, classified in class 435, subclass 69.1, for example.

IV. Claim 31, drawn to a method of identifying inhibitors, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and each of II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of Invention I can be used to label its antigen *in vitro*.

Inventions I and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions do not overlap in scope, since the antibodies and nucleic acids are structurally different type of molecules. Also, the inventions are not obvious variants, since antibodies are often described in the literature by their binding attributes rather than their sequences, and the nucleic acid cannot be inferred from a protein's activity. Finally, the inventions are not disclosed as capable of use together and have materially different designs, modes of operation, and effects.

Inventions III and each of II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together. The methods do not require use of the nucleic acids. Also, the invention have different designs, modes of operation, and effects.

Inventions II and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods

do not overlap in scope as they are directed toward achieving different goals. The inventions are also not obvious variants for the same reason. Finally, the two methods are not disclosed as capable of use together and have materially different designs, modes of operation, and effects.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

***Species Part I – the antibody sequence***

This application contains claims directed to the following patentably distinct species:

I-a. the antibody of SEQ ID NO: 2;

I-b. the antibody of SEQ ID NO: 4;

I-c. the antibody of SEQ ID NO: 6;

I-d. the antibody of SEQ ID NO: 8;

I-e. the antibody of SEQ ID NO: 10;

I-f. the antibody of SEQ ID NO: 12;

I-g. the antibody of SEQ ID NO: 14;

I-h. the antibody of SEQ ID NO: 16;

I-i. the antibody of SEQ ID NO: 18;

I-j. the antibody of SEQ ID NO: 20;

I-k. the antibody of SEQ ID NO: 22;

l-l. the antibody of SEQ ID NO: 24;

l-m. the antibody of SEQ ID NO: 26;

l-n. the antibody of SEQ ID NO: 28;

l-o. the antibody of SEQ ID NO: 30;

l-p. the antibody of SEQ ID NO: 31;

l-q. the antibody of SEQ ID NO: 32;

l-r. the antibody of SEQ ID NO: 33;

l-s. the antibody of SEQ ID NO: 34;

l-t. the antibody of SEQ ID NO: 35;

l-u. the antibody of SEQ ID NO: 36;

l-v. the antibody of SEQ ID NO: 37;

l-w. the antibody of SEQ ID NO: 38;

l-x. the antibody of SEQ ID NO: 39;

l-y. the antibody of SEQ ID NO: 40;

l-z. the antibody of SEQ ID NO: 41;

l-aa. the antibody of SEQ ID NO: 42;

l-bb. the antibody of SEQ ID NO: 43;

l-cc. the antibody of SEQ ID NO: 44;

l-dd. the antibody of SEQ ID NO: 45;

l-ee. the antibody of SEQ ID NO: 46;

l-ff. the antibody of SEQ ID NO: 47; and

l-gg. the antibody of SEQ ID NO: 48.

The species are independent or distinct because each sequence defines a separate molecule, requiring a separate search of the sequence and literature databases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

***Species Part II – the nucleic acid sequence***

This application contains claims directed to the following patentably distinct species:

II-a. the nucleic acid of SEQ ID NO: 1;

II-b. the nucleic acid of SEQ ID NO: 3;

II-c. the nucleic acid of SEQ ID NO: 5;

II-d. the nucleic acid of SEQ ID NO: 9;

II-e. the nucleic acid of SEQ ID NO: 11;

II-f. the nucleic acid of SEQ ID NO: 13;

II-g. the nucleic acid of SEQ ID NO: 15;

II-h. the nucleic acid of SEQ ID NO: 17;

II-i. the nucleic acid of SEQ ID NO: 19;

II-j. the nucleic acid of SEQ ID NO: 21;

II-k. the nucleic acid of SEQ ID NO: 23;

II-l. the nucleic acid of SEQ ID NO: 25;

II-m. the nucleic acid of SEQ ID NO: 27; and

II-n. the nucleic acid of SEQ ID NO: 29.

The species are independent or distinct because each sequence defines a separate molecule, requiring a separate search of the sequence and literature databases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 28 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

***Species Part III – the disease***

This application contains claims directed to the following patentably distinct species:

III-a. muscular dystrophy,

III-b. Duchenne's muscular dystrophy,

III-c. muscle atrophy,

III-d. organ atrophy,

III-e. carpal tunnel syndrome,

III-f. congestive obstructive pulmonary disease,

III-g. sarcopenia,

III-h. cachexia,

III-i. muscle wasting syndrome,

III-j. amyotrophic lateral sclerosis,

III-h. syndrome X,

III-i. impaired glucose tolerance,

III-j. trauma-induced insulin resistance,

III-k. type 2 diabetes,

III-l. obesity,

III-m. damaged myocardial muscle,

III-n. damaged diaphragm,

III-o. increasing muscle strength, and

III-p. increasing muscle mass.

The species are independent or distinct because each disease defines a separate patient population, requiring a separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 28 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER